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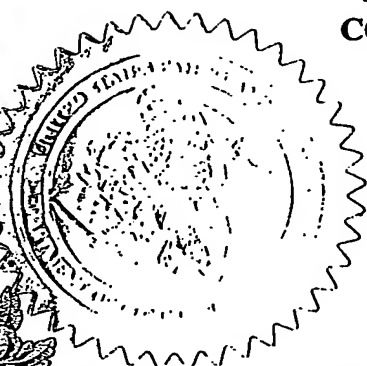
November 02, 2004


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APPLICATION NUMBER: 60/515,978

FILING DATE: *October 29, 2003*

By Authority of the  
COMMISSIONER OF PATENTS AND TRADEMARKS



  
M. K. HAWKINS  
Certifying Officer

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16805 U.S. PTO

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PTO/SB/18 (08-03)

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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. **EL967332653US**

15757 U.S. PTO  
60/515978

102903

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
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Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
CLINICAL ANALYTICS SYSTEM					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number:		26530			
OR					
<input type="checkbox"/> Firm or Individual Name					
Address					
Address					
City		State		Zip	
Country		Telephone		Fax	
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		26		<input checked="" type="checkbox"/> CD(s), Number	
<input type="checkbox"/> Drawing(s) Number of Sheets				<input checked="" type="checkbox"/> Other (specify) Affirmation of	
<input type="checkbox"/> Application Date Sheet. See 37 CFR 1.76				copies of discs	
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE Amount (\$)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees.					
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing deficiencies		12-0400		\$80.00	
<input type="checkbox"/> fees or credit any overpayment to Deposit Account Number:					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are:					

(Page 1 of 2)

Respectfully submitted,

Date **October 29, 2003**

SIGNATURE

*Brian W. Hameder*

REGISTRATION NO. **45613**

TYPED or PRINTED NAME

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(if appropriate)

Docket Number: **CJ-3420 BWH**

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**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## **AFFIRMATION**

I, MARCUS GALLIE, of the firm Ridout & Maybee, LLP, affirm that the compact discs submitted hereto with the provisional application in the United States Patent and Trademark Office for a CLINICAL ANALYTICS SYSTEM and labelled Copy 1 and Copy 2 are true and identical copies.



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Marcus Gallie

## **CLINICAL ANALYTICS SYSTEM**

### **Keywords for searching**

eTrials

PDA Trials

Handheld trials

Handheld randomization

Electronic randomization

Clinical Trials Software

Web Trials

### **Products that will use this Invention**

The inventions listed below are intended to interact with one another but they could be used in conjunction with existing third party products. Cases where we see this potentially happening will be labeled below.

### **Brief Description of the Invention and Problem Solved**

Clinical Analytics (CA) is a suite of web, Palm and telephone based applications that are used in the conduct of clinical trials. CA allows clinical trial operators to capture and manage and monitor patient data electronically in real time. There are multiple aspects and benefits of using CA within a clinical trial that differentiate it from what is currently available elsewhere. A non-exhaustive list includes:

1. The CA clinical trials data capture and management system (eDMS) integrates intelligent web forms housed within a secure web site, smart forms running on Palm PDAs and telephone touch-tone access to provide multiple input/output interfaces into a single, centralized data management center. Through these interfaces clinical researchers can input patient data, monitor study data in real time, randomize patients involved in clinical trials and receive integrated lab results.
2. The basis of the smart electronic case report forms (eCRFs) that are accessed through the Palm and Web interfaces is a highly specialized XML™ specification. The specification allows study coordinators to define the basic content and layout of their eCRFs but it also allows the specification of highly dynamic behavior that goes far beyond anything achievable using conventional

paper-based forms. CA's XML™ spec allows the definition of boundary conditions for each response on the form which, when realized in a "live" form assist in preventing bad data at the source. The spec also allows automated skip logic to be defined and custom calculation scripts to be embedded in the electronic forms.

3. Deploying case report forms, either on paper or electronically to multiple platforms is a operational, time consuming and error prone task. The CA engine, using a single eCRF or collection of eCRFs generated with the CA XML™ spec can automatically generate and deploy code for the eCRF to both Web (e.g. IIS – Internet Information Server), telephone IVR (interactive voice response) and PDA (e.g. Palm) platforms. This means that once the form is authored or updated, investigators can have their new forms deployed to the field within minutes on both Palm and Web platforms. This represents a very significant time savings to investigators. It also removes the risk that some investigators in the field may be working from outdated copies of the forms.
4. Randomized Controlled Clinical trials require that patients be randomly placed into different branches of the study. The CA eDMS allows investigators to "randomize" a patient in one of three ways:
  - 1) through the web interface;
  - 2) using the PDA (Palm); or
  - 3) through an automated phone system.Regardless of the interface used, the randomization code comes from the same centralized service and the results are instantly stored in the study database. This greatly facilitates randomization across multiple sites. Randomization has traditionally been done with paper envelope systems or with phone services not integrated with the study database. These are prone to error and data loss.
5. Because data is stored centrally, patient data can be tracked in real time both through the web and on the Palm. This allows study coordinators to monitor recruitment rates much more closely than with manual systems. It also adds significantly to patient safety since adverse events or trends can be recorded, tracked and acted on in real time. Again, this is very difficult to do with traditional systems.
6. The centralized eDMS provides a full transaction audit trail and backup system to ensure that a record of every transaction is kept and that data can always be restored if lost or damaged. This capability is far beyond what could be achieved with paper-based systems.

The inventions outlined in this documents are comprised of various components that make up the Clinical Analytics (CA) product. The source code for example embodiments of these inventions is provided.

## **REFERENCE TO A COMPUTER PROGRAM LISTING COMPACT DISK APPENDIX**

A computer program listing appendix is included with this application and the entire contents of the computer program listing appendix is incorporated herein by reference.

Accompanying this application is a single CDROM which contains program listings which implement a preferred embodiment of the invention. The CDROM has four subdirectories, "*ASP Source*", "*FastDaemon*", "*Telephone*" and "*XML Forms*". Due to the large quantity of files, amounting to a total of 387 files in all, the specific files in each of the directories and subdirectories are listed in an appendix at the end of this disclosure.

A portion of the disclosure recited in the specification contains material which is subject to copyright protection. Specifically, a Computer Program Listing Appendix in accordance with 37 CFR Section 1.52 is included that lists source code instructions for a process by which the present invention is practiced in a computer system. The copyright owner has no objection to the facsimile reproduction of the specification as filed in the Patent and Trademark Office. Otherwise all copyright rights are reserved.

## Platform Independent XML Specification

The platform neutral specifications of the electronic case report forms used in a clinical trial (eCRFs) is stored in XML format. An XML document is specific to each CRF and includes information such as: dependencies on other CRFs, mapping to database tables, whether duplicate records are allowed for that CRF, a display name for the eCRF, and the type of eCRF (e.g., a screening form, a post-randomization form, a termination form). Within the eCRF specification are entries for each item within the form. An item may be a question or a heading. Questions include information items such as the wording of the question, the type of question, the response categories, the coding scheme to be used for storing information in the database, enabled skip logic (dependencies on other questions), valid ranges, help information, consistency checks, calculations, missing data value, formatting information, annotation information, and the mapping to database tables and fields.

The XML specification holds customized scripting associated with various events that occur during the display of questions and the user interaction with questions. The scripts implement custom functionality that cannot be specified through the standard XML schema. The scripts are device specific (i.e., part of the XML tags includes an indication of the target device because the scripting capabilities on different devices are not necessarily the same).

The XML specification is included as *XML Documentation.doc* in folder *XML Forms*. The code that defines and interprets the XML spec can be found in folder *XML Forms*.

## Commercial Value

The ability to have one comprehensive specification for a CRF facilitates the updating these forms. Changes and protocol amendments are constant throughout a trial and investigators expect rapid updates in the field. A single specification ensures that there are no inconsistencies in forms across devices that are deployed in the field (i.e., they all use the same specification), and makes version control of forms very easy. Both of the above reduce the cost of conducting the trial and ensure the rapid propagation of changes. Keeping forms up to date is also important in ensuring patient safety.

Having a single specification also makes it possible for non-developers to maintain the eCRF specifications themselves, hence offloading some of the trial maintenance and

management tasks to less expensive resources. Again, this can lead to nontrivial reductions in cost and time for making changes during a trial.

### **Single Button Deploy of PDA and Web-based Forms – Description**

All live forms on all devices (e.g., desktop browser, or a PDA) are generated automatically from the XML specifications. This is done with a single click of the button. The web pages are generated automatically when a page is requested. The PDA forms are updated the next time a user performs a hotsync on their device.

The dynamically generated web forms are comprised of ASP, HTML and JavaScript<sup>®</sup> code and interact with an IIS application server.

The dynamically generated PDA forms interact with a centralized synchronization server that, in turn, interacts with the centralized CA server.

The code that defines and interprets the XML spec can be found in folder *XML Forms*.

### **Commercial Value**

Making changes to and redeploying CRFs and eCRF is one of the largest contributors to the operation cost of deploying a clinical trial. Trial sites (typically hospitals) tend to be geographically dispersed which complicates the distribution of updated forms in addition to the problem of assuring that all sites are using the latest version. With electronic trial packages that are less sophisticated than CA, changing electronic forms typically entails hand editing HTML and JavaScript<sup>®</sup> code, updating a database schema, recoding PDA software and having the sites update their installed software. This process can add months to the length of a clinical trial and can add a great deal of cost to the organization running it. The ability to quickly redeploy forms across all platforms offers very high cost savings as well as strategic and patient value in terms of completing trials more quickly.



## **Handheld Randomization**

Randomization is one of the most critical activities in a clinical trial because this is what distinguishes it from less rigorous scientific methods. However, in clinical settings where nurses or research assistants need to randomize a new patient for entry into a trial, being able to randomize quickly using a mobile device is an advantage.

Handheld randomization allows a PDA to connect to the remote randomization server through a secure Internet connection and get the next randomization number/code. This process typically takes less than a minute. The system also verifies that the potential participant meets all inclusion criteria and does not meet any exclusion criteria. This provides an additional safety mechanism to avoid ineligible patients being enrolled in a trial. In settings where there is a wireless network, handheld randomization provides the ultimate flexibility.

TrialStat employs two methodologies for handheld randomization.

TrialStat's Simple Randomization works the following way:

- 1) When the user hotsyncs their Palm device remotely a custom application is started on the server to populate the server side database with data from the Palm based eCRFs and to send updated form information back to the Palm. In addition, if the user has requested a randomization code or codes and additional flag equating to a single data cell is also transmitted and populated to the database.
- 2) When a randomization flag is populated in the database for a patient, a database trigger is fired to retrieve the next available randomization code from a pre-populated randomization table and place it in the patient data record.
- 3) The next time the user synchronizes their Palm, the newly populated randomization data is sent to the Palm to allow the user to determine if the patient is included or excluded.

TrialStat's Advanced Randomization works the following way:

- 1) When the user hotsyncs their Palm device remotely a custom application is started on the server to populate the server side database with data from the Palm based eCRFs and to send updated form information back to the Palm. In addition, if the user has requested a randomization code or codes and additional flag equating to a single data cell is also transmitted and populated to the database.

- 2) When a randomization flag is populated in the database for a patient, a database trigger is fired to retrieve the next available randomization code from a pre-populated randomization table and place it in the patient data record.

When the first trigger retrieves the randomization code from the randomization table a second trigger associated with the randomization table is fired. The second trigger halts the synchronization process until the new randomization code is populated in the patient record. Once this has occurred the second trigger terminates and the synchronization process completes with the new randomization code being transmitted to the users Palm.

### **Commercial Value**

The ability to accurately and quickly randomize a patient from any location reduces the chances that an eligible participant is missed, and this helps ensure that the recruitment targets for a trial are met and that the trial finishes on time. Delays in trial completion can be very expensive for sponsors. In addition, the safety mechanisms that ensure only eligible patients are enrolled reduce the risks of harm to patients and provides a precise audit trail of all decisions that are made. Maximizing patient safety is a clear advantage that such a system can deliver.

The synchronization routines involved in handheld randomization can be found in folder *FastDaemon*.

## **Handheld Monitoring of Trials**

As a trial progress, it is important for site coordinators and research assistants to be able to monitor recruitment rates (overall and by center), and to be able to track the exact status of each participant in the trial (i.e., which forms has that participant completed thus far and what forms need to be completed).

The CA system provides precise tracking on the handheld. Users with the appropriate permissions can find out the basic demographics for each patient, their randomization code/number, and which forms that have been completed thus far. This information is updated on the handheld every time the handheld is hotsync'ed.

## **Commercial Value**

For large trials where tens of forms have to be completed for each patient over an extended period of time that can last years, the traditional paper approach does not allow the site coordinators and research assistants to keep track in real-time of each patient. This becomes even more pronounced when there are multiple individuals entering data on the same patient with each holding a subset of the forms (i.e., no centralized repository of information about each patient). The regularly updated handheld provides a capability that is not readily available otherwise. This primarily reduces the chances of errors. Some of the errors may harm the patient (e.g., doing another unnecessary test because the nurse did not know that that data had already been collected), to unnecessary procedures. Other types of errors will simply waste time (e.g., complete the same form more than once for the same patient) and reduce data quality (e.g., some forms are missed altogether and this increases the chances that all data on that patient is wasted).

Safety, data quality, and safety are key measures of success of a clinical trial and this capability has a multivariate effect on all of them.

## **Trial Management Integrated Suite**

The integrated suite provides all of the above features as well as other features that make it much easier for a large team of investigators and coordinators to collaborate in the conduct of a clinical trial. These collaborative features include a forum with a fine permission structure, a secure instant messaging system among trial managers, a document management system that allows the categorizing and archiving of documents, and a version control system that allows multiple people to collaborate in the production of a document.

From a trial's inception there are many documents that are shared among the trial managers and the investigators (the trial team). These can be drafts of the CRFs (i.e., the data collection forms), drafts of the protocol, amendments, instructions to the sites, REB (Research Ethics Board) letters, and regulatory submissions. Some of these documents are sensitive and some are proprietary. Therefore, a secure way to collaborate and share this information from the inception of a trial is critical.

In the past the trial team exchanged documents by email. In addition to the serious security problems that this entails, email does not easily control versions and stop multiple people from overwriting each other's work. Plus, email does not provide an audit trail. The same applies to discussions and communications among the trials team. Finally, material that is distributed to all of the sites gets lost in personal emails and becomes harder to find at a later date (e.g., newsletters).

The integrated collaboration features in the CA system allow the trials team to post material to all of the sites and everyone one knows where that information is. The changes to that information are tracked throughout its history with versions and people who made changes. All of this is achieved in a secure environment. Permissions on who can read and edit each piece of information is controlled explicitly.

## **Commercial Value**

The first benefit from this collaboration system is that it helps manage the large amounts of documents that are generated during a trial. This saves time by allowing users to find and search large amounts of information rather quickly. In addition, the security provided within the CA system ensures that no proprietary information nor private patient information is transmitted in open networks (i.e. data is protected). This reduces the

chances of breaking laws and regulations. Both of the above can save considerable money to the sponsors of the trial.

In addition, the integration of these collaboration features with the data collection and management system in the CA system means that users can manage the whole trial from one console without having to switch systems or transfer data from one place to another. This reduces their learning burden and ensures that there are no 'gaps' where secure information is being transferred between systems in an insecure fashion.

Many hospitals share information by having a shared drive that everyone can access. This results in confidential information being accessible by anyone and even worse, being modified and deleted by anyone. Since shared drives do not have a tracking mechanism, it is not possible to easily recover changes nor to determine who has made what changes. This has resulted in the loss and corruption of data in the past, as well as security breaches. The CA moves the sites away from this archaic and dangerous way of managing information related to a trial.

The complete source for the integrated suite can be found in folder *ASP Source*.

## **Real-Time Cross Center Analysis**

This feature in the CA system allows the trial manager to compare in real-time the progress of all sites in a single table on various parameters. This real time ranking by recruitment rates, withdrawal rates, enrollment rates, meeting recruitment targets, and form completion statistics allows a project manager to immediately see which sites are performing well and which ones are under-performing. Such feedback allows the identification of site problems early and increases the chances of being able to take remedial action before a small problem puts the whole study in jeopardy.

### **Commercial Value**

The ability to identify issues, such as recruitment problems, early in a trial ensures that the trial managers can take remedial action and avoid not reaching recruitment targets on time. This is critical for stakeholders and sponsors since delays in the completion of trials can be very expensive.

In addition, the identification of remarkable results (e.g., very rapid recruitment) may be an indicator of problems (e.g., data collection or data entry problems). Again, the ability to catch these at the very beginning of a study can ensure that fewer bad or unbelievable data are collected and that staff are either trained or changed before small errors escalate.

The source code for the cross-center reporting is in the following files:

- *ASP Source/ul1/dashboard.asp* is the main file used for real time dashboard generation; and
- *ASP Source/ul1/ExportData.asp* is used to generate real-time Excel sheet.

## **Server Side Data Validation Using Triggers**

Based on a specification provided by the principal investigator, real-time validation of data as it is entered into the database is being performed. For example, checks are performed for unlikely values or for values that require immediate attention (e.g., extreme values on certain measurements). These extreme values may be indicators of very sick patients or patients who need special attention. The validation conditions are expressed as rules and whenever the rule is triggered an email is sent to the person in charge to examine the data more carefully. This means that the availability of information is immediate. The same information can be sent to multiple people and through the internal CA instant messaging system.

These validation rules are implemented as database triggers that are customized for each trial and defined in the XML specification.

### **Commercial Value**

From a safety and data quality perspective the availability of real-time triggers provides an important advantage. Potential patient safety problems are identified right away, reducing the chances of harm being done. In addition, complex data quality validation rules can be checked every time a new data element is entered. If even a single data item for a patient (e.g., on a primary outcome) is invalid, this may result in all of that patient's data being discarded. Therefore, good data quality reduces the chances of a trial being a failure (i.e., if enough patient data are discarded there will be insufficient statistical power to identify an effect even if one exists).

## **Client Side Data Validation Using XML Generated JavaScript®**

Based on a specification provided by the principal investigator, real-time validation of data as it is entered into an eCRF may be performed within the browser environment. For example, checks are performed for out-of-bounds values or for values that require correction. The eCRF evaluates data as it is input and alerts the user immediately if bad data is entered.

The validation is performed by JavaScript® routines that is generated from the XML spec in real time as the page is displayed.

### **Commercial Value**

Catching data errors at the point of entry not only ensures better quality of data, it also make the correction of bad date more efficient and less expensive. In addition, using eCRFs that provide immediate feedback helps to accelerate learning and adoption of the forms by investigators.

The source code for client side validation is in folders *XML Forms* and *ASP Source*.



## **Integrated Randomization**

Randomization in the CA system can occur in one of three ways: handheld (discussed above), web, and telephone. All of these systems are integrated such that the same sequence of randomization codes is used, irrespective of the randomization device. All three methods also have the capability to track randomization progress, irrespective of how randomization was performed.

This gives the end-user complete flexibility to randomize using the most convenient device. If the user is at his/her office in front of a desktop then web randomization may be the best option. If in an ICU where no Internet access is available and there is no wireless network, telephone randomization would be available. Finally, if the user is on rounds with no easy access to a desktop nor a telephone, randomization using a wireless handheld device would be available.

All three modes record the time and the user who performed the randomization. All three modes ensure allocation concealment, which is required in all randomized controlled trials.

## **Commercial Value**

The flexibility make it possible to deploy the CA system across a wide range of situations and settings. This means an initial investment in the CA system can be spread across multiple trials in the same hospital. This reduces the overall cost per trial from using electronic data collection and management.

Also, should investigators wish to use only the randomization features and not the data collection and management features, this can be easily accommodated with the integrated randomization system. The ability to focus only on randomization allows hospitals to introduce electronic systems in their trials gradually - which may have an adoption advantage.

The code for the randomization can be found in the following locations.

- for the Telephone Interface in folder: *Telephone*
- for Web and PDA in folder: *FastDaemon*

# COMPUTER PROGRAM LISTING COMPACT DISK APPENDIX

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Volume Serial Number is EA27-05C1

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10/16/2003	03:48p		7,359	ViewRandomization.asp
10/16/2003	03:48p		2,968	ViewScreeningPatients.asp
10/16/2003	03:48p		679	ViewSpecs.pasp
10/16/2003	03:48p		1,499	ViewSubForm.asp
		56 File(s)	167,799	bytes

## Directory of D:\ASP Source\ul1\ca-includes

10/24/2003	01:53p	<DIR>	.
10/24/2003	01:53p	<DIR>	..
10/16/2003	03:49p		2,403 loader.js
		1 File(s)	2,403 bytes

## Directory of D:\ASP Source\ul1\CAHelp

10/24/2003	02:20p	<DIR>	.
10/24/2003	02:20p	<DIR>	..
10/16/2003	03:48p		9,102 bsscftp.ds
10/16/2003	03:48p		6,588 CAHelp.htm

10/16/2003	03:48p		3,137	CAHelp.log
10/16/2003	03:48p		2,313	CAHelp_csh.htm
10/16/2003	03:48p		2,315	CAHelp_rhc.htm
10/24/2003	01:53p	<DIR>		Changing
10/24/2003	01:53p	<DIR>		Creating
10/16/2003	03:48p		5,950	cshdat_robohelp.htm
10/16/2003	03:48p		5,909	cshdat_webhelp.htm
10/16/2003	03:48p		1,619	default.css
10/16/2003	03:48p		9,923	default.skn
10/16/2003	03:48p		2,383	default_ns.css
10/24/2003	01:53p	<DIR>		Editting
10/16/2003	03:48p		407	eHelp.xml
10/16/2003	03:48p		122,450	ehlpdhtm.js
10/24/2003	01:53p	<DIR>		Entering
10/24/2003	01:53p	<DIR>		Exchanging
10/24/2003	01:53p	<DIR>		Exporting_Data
10/24/2003	01:53p	<DIR>		FAQ
10/16/2003	03:48p		146	folder95c.gif
10/16/2003	03:48p		153	folder95o.gif
10/24/2003	01:53p	<DIR>		Getting_Started
10/16/2003	03:48p		4,726	Getting_Started.htm
10/16/2003	03:48p		3,335	image2.gif
10/16/2003	03:48p		3,571	logo-on-white.gif
10/16/2003	03:48p		1,687	powered_logo_transparent.gif
10/24/2003	01:53p	<DIR>		Responding
10/24/2003	01:53p	<DIR>		Viewing_Reports
10/24/2003	01:53p	<DIR>		ViewLib
10/16/2003	03:48p		87,764	webhelp.cab
10/16/2003	03:49p		132,680	webhelp.jar
10/16/2003	03:49p		774	whskin_info.htm
10/16/2003	03:49p		9,930	whskin_papplet.htm
10/16/2003	03:49p		1,738	whskin_mbars.htm
10/16/2003	03:49p		1,648	whskin_pdhtml.htm
10/16/2003	03:49p		4,024	whskin_tbars.htm
10/16/2003	03:49p		5,143	whskin_plist.htm
10/24/2003	01:53p	<DIR>		whdata
10/16/2003	03:49p		10,134	whestart.ico
10/16/2003	03:49p		1,288	whfbody.htm
10/16/2003	03:49p		1,081	whfdhtml.htm
10/16/2003	03:49p		3,210	whfform.htm
10/16/2003	03:49p		18,595	whfhost.js
10/16/2003	03:49p		5,179	whform.js
10/16/2003	03:49p		2,003	whframes.js
10/16/2003	03:49p		1,235	whgbody.htm
10/24/2003	01:53p	<DIR>		whgdata
10/16/2003	03:49p		2,580	whgdef.htm
10/16/2003	03:49p		3,693	whgdhtml.htm
10/16/2003	03:49p		5,002	whghost.js
10/16/2003	03:49p		24,500	whhhost.js
10/16/2003	03:49p		8,837	whibody.htm
10/16/2003	03:49p		1,071	whidhtml.htm
10/16/2003	03:49p		2,286	whiform.htm
10/16/2003	03:49p		10,939	whihost.js
10/16/2003	03:49p		10,826	whlang.js
10/16/2003	03:49p		2,003	whmozemu.js
10/16/2003	03:49p		1,666	whmsg.js
10/16/2003	03:49p		1,066	whnjs.htm

10/16/2003	03:49p	11,295	whphost.js
10/16/2003	03:49p	650	whproj.htm
10/16/2003	03:49p	1,382	whproj.js
10/16/2003	03:49p	152	whproj.xml
10/16/2003	03:49p	1,306	whproxy.js
10/16/2003	03:49p	9,903	whres.xml
10/16/2003	03:49p	10,134	whrstart.ico
10/16/2003	03:49p	1,983	whskin_banner.htm
10/16/2003	03:49p	283	whskin_blank.htm
10/16/2003	03:49p	4,566	whskin_frmset01.htm
10/16/2003	03:49p	1,748	whskin_frmset010.htm
10/16/2003	03:49p	10,134	whstart.ico
10/16/2003	03:49p	5,474	whstart.js
10/16/2003	03:49p	3,265	whstub.js
10/16/2003	03:49p	2,793	whst_topics.xml
10/16/2003	03:49p	45,140	whthbar.js
10/16/2003	03:49p	1,612	whthdhtml.htm
10/16/2003	03:49p	27,574	whthost.js
10/16/2003	03:49p	14,807	whthopic.js
10/16/2003	03:49p	23,356	whth_abge.jpg
10/16/2003	03:49p	24,385	whth_abgi.jpg
10/16/2003	03:49p	22,665	whth_abgw.jpg
10/16/2003	03:49p	8,785	whth_abte.jpg
10/16/2003	03:49p	6,985	whth_abti.jpg
10/16/2003	03:49p	7,382	whth_abtw.jpg
10/16/2003	03:49p	188	whth_fts_h.gif
10/16/2003	03:49p	188	whth_fts_n.gif
10/16/2003	03:49p	142	whth_glo_h.gif
10/16/2003	03:49p	142	whth_glo_n.gif
10/16/2003	03:49p	260	whth_go.gif
10/16/2003	03:49p	842	whth_hide.gif
10/16/2003	03:49p	168	whth_idx_h.gif
10/16/2003	03:49p	168	whth_idx_n.gif
10/16/2003	03:49p	1,405	whth_logol.gif
10/16/2003	03:49p	1,393	whth_logo2.gif
10/16/2003	03:49p	73	whth_next.gif
10/16/2003	03:49p	73	whth_next_g.gif
10/16/2003	03:49p	73	whth_prev.gif
10/16/2003	03:49p	73	whth_prev_g.gif
10/16/2003	03:49p	43	whth_spac.gif
10/16/2003	03:49p	846	whth_sync.gif
10/16/2003	03:49p	285	whth_tab0.gif
10/16/2003	03:49p	237	whth_tab1.gif
10/16/2003	03:49p	226	whth_tab2.gif
10/16/2003	03:49p	209	whth_tab3.gif
10/16/2003	03:49p	198	whth_tab4.gif
10/16/2003	03:49p	221	whth_tab5.gif
10/16/2003	03:49p	212	whth_tab6.gif
10/16/2003	03:49p	236	whth_tab7.gif
10/16/2003	03:49p	225	whth_tab8.gif
10/16/2003	03:49p	911	whth_toc3.gif
10/16/2003	03:49p	953	whth_toc4.gif
10/16/2003	03:49p	204	whth_toc_h.gif
10/16/2003	03:49p	195	whth_toc_n.gif
10/16/2003	03:49p	973	whth_ws.gif
10/16/2003	03:49p	949	whth_ws_g.gif
10/16/2003	03:49p	9,495	whthutils.js

10/16/2003 03:49p 1,136 whver.js  
 104 File(s) 817,310 bytes

Directory of D:\ASP Source\ul1\CAHelp\Changing

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 119 bsscftp.ds  
 10/16/2003 03:49p 4,835 Changing\_Your\_Settings\_Introduction.htm  
 2 File(s) 4,954 bytes

Directory of D:\ASP Source\ul1\CAHelp\Creating

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 111 bsscftp.ds  
 10/16/2003 03:49p 4,845 Creating\_A\_CRF\_Introduction.htm  
 2 File(s) 4,956 bytes

Directory of D:\ASP Source\ul1\CAHelp\Editiing

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 117 bsscftp.ds  
 10/16/2003 03:49p 4,869 Editing\_Data\_On-line\_Introduction.htm  
 2 File(s) 4,986 bytes

Directory of D:\ASP Source\ul1\CAHelp\Entering

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 121 bsscftp.ds  
 10/16/2003 03:49p 4,885 Entering\_Data\_On\_The\_PDA\_Introduction.htm  
 2 File(s) 5,006 bytes

Directory of D:\ASP Source\ul1\CAHelp\Exchanging

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 144 bsscftp.ds  
 10/16/2003 03:49p 4,977  
 Exchanging\_Information\_With\_Other\_Investigators\_Introduction.htm  
 2 File(s) 5,121 bytes

Directory of D:\ASP Source\ul1\CAHelp\Exporting\_Data

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 111 bsscftp.ds  
 10/16/2003 03:49p 4,845 Exporting\_Data\_Introduction.htm  
 2 File(s) 4,956 bytes

Directory of D:\ASP Source\ul1\CAHelp\FAQ

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 100 bsscftp.ds

10/16/2003 03:49p 4,824 FAQ\_Introduction.htm  
 2 File(s) 4,924 bytes

Directory of D:\ASP Source\ul1\CAHelp\Getting\_Started

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 99 bsscftp.ds  
 10/16/2003 03:49p 4,930 Getting\_Started.htm  
 10/16/2003 03:48p <DIR> \_notes  
 2 File(s) 5,029 bytes

Directory of D:\ASP Source\ul1\CAHelp\Getting\_Started\\_notes

10/16/2003 03:48p <DIR> .  
 10/16/2003 03:48p <DIR> ..  
 0 File(s) 0 bytes

Directory of D:\ASP Source\ul1\CAHelp\Responding

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 119 bsscftp.ds  
 10/16/2003 03:49p 4,877 Responding\_To\_Messages\_Introduction.htm  
 2 File(s) 4,996 bytes

Directory of D:\ASP Source\ul1\CAHelp\Viewing\_Reports

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 112 bsscftp.ds  
 10/16/2003 03:49p 4,849 Viewing\_Reports\_Introduction.htm  
 2 File(s) 4,961 bytes

Directory of D:\ASP Source\ul1\CAHelp\ViewLib

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 116 bsscftp.ds  
 10/16/2003 03:49p 4,865 Viewing\_The\_Library\_Introduction.htm  
 2 File(s) 4,981 bytes

Directory of D:\ASP Source\ul1\CAHelp\whdata

10/24/2003 01:53p <DIR> .  
 10/24/2003 01:53p <DIR> ..  
 10/16/2003 03:49p 1,984 bsscftp.ds  
 10/16/2003 03:49p 437 whftdata.js  
 10/16/2003 03:49p 1,203 whftdata0.htm  
 10/16/2003 03:49p 1,130 whftdata0.xml  
 10/16/2003 03:49p 302 whfts.htm  
 10/16/2003 03:49p 890 whfts.js  
 10/16/2003 03:49p 180 whfts.xml  
 10/16/2003 03:49p 646 whfwdata.js  
 10/16/2003 03:49p 1,173 whfwdata0.htm  
 10/16/2003 03:49p 1,451 whfwdata0.xml  
 10/16/2003 03:49p 390 whgdata.js

10/16/2003	03:49p	237 whglo.htm
10/16/2003	03:49p	668 whglo.js
10/16/2003	03:49p	71 whglo.xml
10/16/2003	03:49p	1,730 whidata.js
10/16/2003	03:49p	234 whidx.htm
10/16/2003	03:49p	668 whidx.js
10/16/2003	03:49p	67 whidx.xml
10/16/2003	03:49p	1,159 whtdata.js
10/16/2003	03:49p	1,610 whtdata0.htm
10/16/2003	03:49p	1,638 whtdata0.xml
10/16/2003	03:49p	265 whtoc.htm
10/16/2003	03:49p	492 whtoc.js
10/16/2003	03:49p	83 whtoc.xml
24 File(s)		18,708 bytes

## Directory of D:\ASP Source\ul1\CAHelp\whgdata

10/24/2003	01:53p	<DIR>	.
10/24/2003	01:53p	<DIR>	..
10/16/2003	03:49p	3,408	bsscftp.ds
10/16/2003	03:49p	67	whexpbar.gif
10/16/2003	03:49p	12,636	whlstf0.htm
10/16/2003	03:49p	2,123	whlstf10.htm
10/16/2003	03:49p	2,378	whlstf11.htm
10/16/2003	03:49p	2,208	whlstf12.htm
10/16/2003	03:49p	2,123	whlstf13.htm
10/16/2003	03:49p	2,123	whlstf14.htm
10/16/2003	03:49p	2,123	whlstf15.htm
10/16/2003	03:49p	2,123	whlstf16.htm
10/16/2003	03:49p	2,123	whlstf17.htm
10/16/2003	03:49p	1,675	whlstg0.htm
10/16/2003	03:49p	1,649	whlsti0.htm
10/16/2003	03:49p	3,631	whlstt0.htm
10/16/2003	03:49p	3,792	whlstt1.htm
10/16/2003	03:49p	3,790	whlstt10.htm
10/16/2003	03:49p	3,758	whlstt11.htm
10/16/2003	03:49p	3,797	whlstt2.htm
10/16/2003	03:49p	3,781	whlstt3.htm
10/16/2003	03:49p	3,793	whlstt4.htm
10/16/2003	03:49p	3,801	whlstt5.htm
10/16/2003	03:49p	3,847	whlstt6.htm
10/16/2003	03:49p	3,781	whlstt7.htm
10/16/2003	03:49p	3,797	whlstt8.htm
10/16/2003	03:49p	3,783	whlstt9.htm
10/16/2003	03:49p	387	whnvf30.htm
10/16/2003	03:49p	581	whnvf31.htm
10/16/2003	03:49p	583	whnvf32.htm
10/16/2003	03:49p	596	whnvf33.htm
10/16/2003	03:49p	2,646	whnvl31.htm
10/16/2003	03:49p	3,504	whnvl32.htm
10/16/2003	03:49p	1,712	whnvl33.htm
10/16/2003	03:49p	503	whnvp30.htm
10/16/2003	03:49p	499	whnvp31.htm
10/16/2003	03:49p	575	whnvp32.htm
10/16/2003	03:49p	505	whnvp33.htm
10/16/2003	03:49p	1,931	whnvt30.htm
10/16/2003	03:49p	1,973	whnvt31.htm



```

10/16/2003 03:49p          2,012 whnvt32.htm
10/16/2003 03:49p          2,023 whnvt33.htm
10/16/2003 03:48p      <DIR>      _notes
          40 File(s)          102,140 bytes

```

Directory of D:\ASP Source\ul1\CAHelp\whgdata\\_notes

```

10/16/2003 03:48p      <DIR>      .
10/16/2003 03:48p      <DIR>      ..
          0 File(s)          0 bytes

```

Directory of D:\ASP Source\ul1\images

```

10/24/2003 01:53p      <DIR>      .
10/24/2003 01:53p      <DIR>      ..
10/16/2003 03:49p          392 admin.gif
10/16/2003 03:49p      2,037 analytics_logo.gif
10/16/2003 03:49p          249 back.gif
10/16/2003 03:49p      2,248 banner.gif
10/16/2003 03:49p          197 bar.gif
10/16/2003 03:49p      1,080 book.gif
10/16/2003 03:49p      1,281 bshelf.gif
10/16/2003 03:49p          254 btm_nav.gif
10/16/2003 03:49p          217 ButtonBG.gif
10/16/2003 03:49p          43 clearpixel.gif
10/16/2003 03:49p          306 computer.gif
10/16/2003 03:49p          340 data.gif
10/16/2003 03:49p          239 dice.gif
10/16/2003 03:49p          945 editicon.gif
10/16/2003 03:49p          129 excel.gif
10/16/2003 03:49p          950 exporticon.gif
10/16/2003 03:49p      1,097 face.gif
10/16/2003 03:49p          255 faq.gif
10/16/2003 03:49p      82,078 globe.gif
10/16/2003 03:49p          115 graph.gif
10/16/2003 03:49p          238 grayimg1.gif
10/16/2003 03:49p          166 grayimg2.gif
10/16/2003 03:49p           86 grayimg3.gif
10/16/2003 03:49p          197 grayimg4.gif
10/16/2003 03:49p          396 hadmin.gif
10/16/2003 03:49p          279 handshake.gif
10/16/2003 03:49p          358 hdata.gif
10/16/2003 03:49p          229 help.gif
10/16/2003 03:49p          342 helpicon.gif
10/16/2003 03:49p          422 hlibrary.gif
10/16/2003 03:49p          421 hreports.gif
10/16/2003 03:49p          427 hsettings.gif
10/16/2003 03:49p          371 htools.gif
10/16/2003 03:49p          275 img1.gif
10/16/2003 03:49p          161 img2.gif
10/16/2003 03:49p          255 img3.gif
10/16/2003 03:49p          399 library.gif
10/16/2003 03:49p           43 littlex.gif
10/16/2003 03:49p      1,323 logo.gif
10/16/2003 03:49p          323 logout.gif
10/16/2003 03:49p           77 nav_line.gif
10/16/2003 03:49p           87 newicon.gif

```

10/16/2003	03:49p	383	password.gif
10/16/2003	03:49p	999	pie.gif
10/16/2003	03:49p	1,299	poweredby_icon.gif
10/16/2003	03:49p	1,412	prefs.gif
10/16/2003	03:49p	1,074	report.gif
10/16/2003	03:49p	404	reports.gif
10/16/2003	03:49p	356	scroll_up_enable.gif
10/16/2003	03:49p	335	scroll_disable.gif
10/16/2003	03:49p	354	scroll_down_active.gif
10/16/2003	03:49p	358	scroll_down_enable.gif
10/16/2003	03:49p	351	scroll_up_active.gif
10/16/2003	03:49p	395	settings.gif
10/16/2003	03:49p	200	side_nav.gif
10/16/2003	03:49p	43	spacer.gif
10/16/2003	03:49p	16,515	speed.gif
10/16/2003	03:49p	331	submit.gif
10/16/2003	03:49p	358	tools.gif
10/16/2003	03:49p	250	username.gif
10/16/2003	03:49p	1,005	viewicon.gif
		61 File(s)	127,749 bytes

## Directory of D:\ASP Source\ul1\menu

10/24/2003	01:53p	<DIR>	.
10/24/2003	01:53p	<DIR>	..
10/24/2003	01:53p	<DIR>	admin
10/24/2003	01:53p	<DIR>	data
10/24/2003	01:53p	<DIR>	reports
		0 File(s)	0 bytes

## Directory of D:\ASP Source\ul1\menu\admin

10/24/2003	01:53p	<DIR>	.
10/24/2003	01:53p	<DIR>	..
10/16/2003	03:49p		6,799 fallback.js
10/16/2003	03:49p		14,239 ie4.js
10/16/2003	03:49p		14,494 ie5.js
10/16/2003	03:49p		14,494 ie6.js
10/16/2003	03:49p		2,605 loader.js
10/16/2003	03:49p		19,165 moz1.js
10/16/2003	03:49p		17,242 nn4.js
10/16/2003	03:49p		19,165 nn6.js
		8 File(s)	108,203 bytes

## Directory of D:\ASP Source\ul1\menu\data

10/24/2003	01:53p	<DIR>	.
10/24/2003	01:53p	<DIR>	..
10/16/2003	03:49p		6,656 fallback.js
10/16/2003	03:49p		13,493 ie4.js
10/16/2003	03:49p		13,748 ie5.js
10/16/2003	03:49p		13,748 ie6.js
10/16/2003	03:49p		2,610 loader.js
10/16/2003	03:49p		18,049 moz1.js
10/16/2003	03:49p		16,188 nn4.js
10/16/2003	03:49p		18,049 nn6.js
		8 File(s)	102,541 bytes

## Directory of D:\ASP Source\ul1\menu\reports

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 03:49p 2,917 fallback.js
10/16/2003 03:49p 9,070 ie4.js
10/16/2003 03:49p 9,325 ie5.js
10/16/2003 03:49p 9,325 ie6.js
10/16/2003 03:49p 2,613 loader.js
10/16/2003 03:49p 11,977 moz1.js
10/16/2003 03:49p 10,168 nn4.js
10/16/2003 03:49p 11,977 nn6.js
      8 File(s) 67,372 bytes

```

## Directory of D:\ASP Source\ul2

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 03:49p 1,360 EditData.asp
10/16/2003 03:49p 1,323 NewData.asp
10/16/2003 03:49p 1,017 ViewData.asp
      3 File(s) 3,700 bytes

```

## Directory of D:\ASP Source\ul3

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 03:49p 5,512 AccessLocation.asp
10/16/2003 03:49p 1,170 DeleteSingleLocation.asp
10/16/2003 03:49p 1,146 DeleteSinglePalm.asp
10/16/2003 03:49p 3,929 NewLocation.asp
10/16/2003 03:49p 7,118 NewPalm.asp
10/16/2003 03:49p 4,705 PalmLocation.asp
10/16/2003 03:49p 1,150 preferences.asp
10/16/2003 03:49p 1,092 PrintAccess.asp
10/16/2003 03:49p 1,602 ProjectSpecs.asp
10/16/2003 03:49p 656 Redistribute.asp
10/16/2003 03:49p 4,331 UpdateLocation.asp
10/16/2003 03:49p 4,711 UpdatePalm.asp
10/16/2003 03:49p 3,746 UpdateSingleLocation.asp
10/16/2003 03:49p 7,566 UpdateSinglePalm.asp
      14 File(s) 48,434 bytes

```

## Directory of D:\ASP Source\ul4

```

10/16/2003 03:48p <DIR> .
10/16/2003 03:48p <DIR> ..
      0 File(s) 0 bytes

```

## Directory of D:\ASP Source\ul5

```

10/16/2003 03:48p <DIR> .
10/16/2003 03:48p <DIR> ..
      0 File(s) 0 bytes

```

## Directory of D:\ASP Source\ul6

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 03:49p      783 DeleteForm.asp
10/16/2003 03:49p    7,152 NewForm.asp
10/16/2003 03:49p  10,955 OverWriteForm.asp
10/16/2003 03:49p    4,570 UpdateForm.asp
      4 File(s)      23,460 bytes

```

## Directory of D:\FastDaemon

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 04:13p    86,066 fastdaemon.dll
10/16/2003 04:13p  1,742,935 FastDaemonInstaller.exe
10/16/2003 04:13p      984 fastdaemon.exp
10/16/2003 04:13p    2,646 fastdaemon.lib
10/16/2003 04:13p  140,288 fastdaemon.pdb
10/16/2003 04:13p    1,195 fastdaemon.vbp
10/16/2003 04:13p    3,653 fastdaemonservice.vbr
10/16/2003 04:13p      73 fastdaemon.vbw
10/16/2003 04:13p   102,400 fastdaemonservice.exe
10/16/2003 04:13p    34,975 Service.cls
10/16/2003 04:13p    2,695 ServiceCfg.cls
10/24/2003 01:53p <DIR> Stored procedures
      11 File(s)    2,117,910 bytes

```

## Directory of D:\FastDaemon\Stored procedures

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 04:13p    5,519 sp_add_time_slot_records.sql
10/16/2003 04:13p    3,425 sp_get_strat_sql_string.sql
10/16/2003 04:13p    7,599 sp_randomize.sql
      3 File(s)    16,543 bytes

```

## Directory of D:\Telephone

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 04:57p    75,264 CreatePatient-Instructions-Detailed.doc
10/16/2003 04:57p    45,568 CreatePatient-Instructions-User.doc
10/16/2003 04:57p  4,628,480 May15Backup.acc
10/16/2003 04:57p  4,628,480 RandomizationSystemFirstTry.acc
10/16/2003 04:57p    847,872 RandomizationSystemFirstTryMay27-FINAL-
FINAL.acc
10/16/2003 04:57p    712,704 Randomization_Live_System.acc
10/16/2003 04:57p    12,854 VBScriptBuiltInFunctions.bas
10/16/2003 04:57p  4,628,480 WorkingComputerGenerated.acc
      8 File(s)    15,579,702 bytes

```

## Directory of D:\XML Forms

```

10/24/2003 01:53p <DIR> .
10/24/2003 01:53p <DIR> ..
10/16/2003 03:47p    1,440 caller.asp
10/16/2003 03:47p    6,351 developerDocumentation.xsl

```

10/16/2003	03:47p		916 include.inc
10/24/2003	01:53p	<DIR>	Parsing Tool
10/16/2003	03:47p		20,764 sqlTransform.xsl
10/16/2003	03:47p		6,712 TrialstatXMLSpecDTD.dtd
10/16/2003	03:47p		5,862 userDocumentation.xsl
10/16/2003	03:47p		127,488 XML Documentation.doc
		7 File(s)	169,533 bytes

## Directory of D:\XML Forms\Parsing Tool

10/24/2003	01:53p	<DIR>	.
10/24/2003	01:53p	<DIR>	..
10/16/2003	03:47p		655,360 AspXml.exe
10/16/2003	03:47p		15,442 ParsingTool.asp
10/16/2003	03:47p		23,040 Parsing Tool Setup.doc
10/16/2003	03:47p		43,822 ParsingToolGenericFunctions.inc
		4 File(s)	737,664 bytes

Total Files Listed:		
387 File(s)	20,271,746 bytes	
105 Dir(s)	0 bytes free	

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